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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/043,689

01/10/2002

Peter P. Lee

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

SALVOZA, M FRANCO G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,689

Applicant(s)

LEE, PETER P.

Examiner

M. Franco Salvoza

Art Unit

1648

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

Amendments to the specification are acknowledged. The withdrawal of claims 29-35, 37 and 38 with the possibility of rejoinder is acknowledged as well. Claims 17-28 are pending and were rejected as obvious over prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-20 and 23-28 were rejected under 103(a) as being unpatentable over McCormick et. al. (Journal of Immunology. 1997; 158: 3474-3482) and Meruelo et. al. (U.S. 5,834,589). McCormick teaches a cross linked bispecific antibody that includes 1) a monoclonal antibody specific for bacteria (*Pseudomonas aeruginosa*) that infects the lungs, and 2) an antibody specific for CD18. Meruelo teaches viral receptor proteins comprising antibody fragments specific for a human cell that encompass CD4 and CD21.

Applicant argues Examiner Foley's rejection of these claims using a combination of these references lacked the requisite motivation under 103(a). Applicant cites the narrow motivation of increasing the half life of soluble viral receptors intended to block viral entry into cells.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, applicant's arguments are considered but found unpersuasive. One of ordinary skill in the art creating a product that would block specific viral receptors and increase durability of those ligands would have been motivated to combine these references. The combination of the bacteria-anchored, bispecific antibody with the added viral specificity of substituting CD21 in Meruelo for the antibody specific for CD18 in McCormick confers the added advantage and reliability of tissue-specific targeting of cells in the mucosa to more strongly anchor those blocks to viral receptors. One of ordinary skill in the art would have also had a reasonable expectation of success for doing so based on the references.

MPEP § 2144 specifically states:

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art,

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established scientific principles, or legal precedent established by prior case law (emphasis added).

McCormick's narrow motivation to overcome opsonin-receptor mismatches in the lungs of cystic fibrosis patients does not diminish the rejection based on the combination of references. The use of cross-linked bispecific ligands as an adaptor molecule to both anchor and simultaneously block viral receptors is within the scope of ordinary skill in the art.

Claims 21 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over McCormick et al. and Meruelo et al. as applied to claims 17-20 and 23-28, and further in view of Baba et al. (EMBO Journal. 1996; 15(18): 4789-4797). Baba teaches target specificity to *Staphylococcus aureus* with C-terminal lysostaphin residues.

Applicant once again argues the lack of motivation to modify the bispecific antibodies of McCormick with the viral binding moieties of Meruelo, and Baba does not supply the requisite motivation.

Applicant's arguments are considered but are found unpersuasive. Both the McCormick and Baba references teach bispecific molecules comprising bacterial-specific fragments that specifically target bacteria in the mucosa. The combination of references is proper for the reasons articulated above, and the added combination of the Baba reference provides another obviousness rejection for the additional limitations claims 21 and 22 in modifying those bispecific molecules in regards to C-terminal lysostaphin residues to target hybrid proteins to *Staphylococcus aureus*. One of ordinary skill in the art would have found the motivation to combine the McCormick and Meruelo references in view of Baba since the combination provides the added advantage of tissue specificity using C-terminal lysostaphin residues to target

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hybrid proteins to *Staphylococcus*. In addition, one of ordinary skill in the art would have had a reasonable expectation of success for doing so in light of the combination of references.

There does not appear to be a defect in the combination of references cited above. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art for reasons of record.

CONCLUSION


THIS ACTION IS MADE FINAL. Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



M. Franco Salvoza,
Patent Examiner



JAMES HOUSEL 5/2/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000